

K253377 Expandable Titanium PLIF/TLIF SystemOct 24, 2025
24 days to decisionK253377 · Product code: **MAX** · Orthopedic
Source: <https://www.510kdatabase.net/k253377/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Intervertebral Fusion Device With Bone Graft, Lumbar (MAX)
Date received	Sep 30, 2025
Decision date	Oct 24, 2025
Days to decision	24 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Spectrum Spine, Inc.
Location	Jasper, GA, US
Contact	Scott Baltsen
Website	https://spectrumspine.com
510(k) history	3 submissions · 3 cleared · 2024-2025

Spectrum Spine, Inc. develops spinal implant systems for orthopedic surgery. The company operates with a manufacturing facility in Jasper, US, and focuses on innovative solutions for spinal fusion procedures. The company has received FDA 510(k) clearances from total submissions. All submissions fall within the Orthopedic device category. Spectrum Spine achieved its first clearance in 2024 and most recently in 2025, demonstrating active regulatory engagement. Recent cleared devices include expandable titanium systems for posterior lumbar interbody fusion, as well as lumbar...

REGULATORY CONSULTANT

Consulting firm	MRC Global, LLC
Contact	Christine Scifert

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)

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Device record: <https://www.510kdatabase.net/k253377/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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